

Remarks

The present invention is directed to methods of inhibiting MIF activity and methods of treating or diagnosing rheumatoid arthritis. Claims 3-17, 20-22, 24-25 and 30-40 have been cancelled. Claims 1-2, 18-19, 23, 26-29 and 41-43 are currently pending.

Examiner Interview

Applicants would like to thank Examiner Chung for her attention and helpful comments in a telephone interview on November 10, 2009 regarding the current rejections and claims. In the interview, the Examiner explained the present rejections in detail, and provided suggestions for claim language to meet the standard for enablement. Applicants request reconsideration of the rejections as they apply to the amended claims and earnestly solicit a Notice of Allowance.

Rejections under 35 U.S.C. 112, 1st paragraph

Claims 1-23 and 26-30 are rejected under 35 U.S.C. 112, first paragraph, for allegedly lacking enablement. Applicants respectfully traverse this rejection as it applies to the amended claims.

The Examiner rejects claims 1-23 and 26-30 for lacking enablement specifically due to the many different types of diseases claims in the application which are asserted to all have different mechanisms of action.

Applicants note that claims 1, 2, 18, and 41-43 are directed to “A method of inhibiting activity of MIF...” These claims are not directed to treatment of disease, and accordingly these claims are clearly enabled in light of the amount of in vitro data presented within the specification in respect of the exemplified 1,3-benzimidazol-2-ones of formula (I). As there is

clear teaching in the specification that the compounds as defined in the claim are MIF inhibitors, Applicants respectfully request withdrawal of the rejection of these claims.

The Examiner has rejected claims 19-23 and 26-29 directed to methods of treatment of a disease, and the claims are now amended to recite only Rheumatoid arthritis.

The Examiner is of the opinion that since the prior art does not show the use of small molecules to treat rheumatoid arthritis, then there exists a level of unpredictability. Applicants refer the Examiner to the 2005 research article by Morand et al reporting that a small molecule MIF antagonist has been shown to be effective in a mouse model of rheumatoid arthritis (*Inflammation Research* 54:S90-S91, 2005). Applicants also assert that evidence showing actions of small molecule compounds is not relevant to enable the claimed methods. The previously submitted articles were cited to the Examiner only for the teaching that inhibiting MIF results in therapeutic benefit of these diseases. The scarcity of small molecule inhibition of MIF in the non-patent literature in fact underscores the utility and novelty of the claimed methods.

The evidence presented to demonstrate a therapeutic effect of MIF inhibition should be sufficient to enable that MIF inhibition, whether by small synthetically-derived molecule or biologic compound would also be effective in treating the disease.

In view of these remarks, one of ordinary skill in the art would be able to make and use the claimed invention commensurate with the scope of the amended claims with a reasonable expectation of success, thereby meeting the legal standard for enablement. Withdrawal of this rejection is respectfully requested.

Obviousness-type Double Patenting

Claims 1-23 and 26-30 are rejected for obviousness-type double patenting over claims 1-27 of U.S. Patent Application 12/158,563. Applicants respectfully request deferral of this rejection until allowable subject matter is found in either patent application. At such a time, a terminal disclaimer will be filed if deemed necessary.

Conclusions

Applicants submit that the response herein provides a complete response to the Office Action dated June 15, 2009.

If the Examiner believes there are other issues that may be resolved by telephone interview, or that there are any informalities remaining in the application that may be corrected by Examiner's Amendment, a telephone call to the undersigned is respectfully solicited.

No additional fees are believed due, however the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment of fees to Deposit Account number 11-0980.

Respectfully submitted,

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